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DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 44, 46, and 52

[FAC 2005-78; FAR Case 2012-032; Item IV; Docket No. 2012-0032, Sequence No. 1]

RIN 9000-AM65

Federal Acquisition Regulation; Higher-Level Contract Quality Requirements

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA are issuing a final rule amending the Federal Acquisition Regulation (FAR) to clarify when to use higher-level quality standards in solicitations and contracts. The rule also updates the examples of higher-level quality standards by removing obsolete standards and adding new industry standards that pertain to quality assurance for avoidance of counterfeit items.

DATES: Effective: **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].**

FOR FURTHER INFORMATION CONTACT: Mr. Edward Loeb, Procurement Analyst, at 202-501-0650, for clarification of

content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202-501-4755. Please cite FAC 2005-78, FAR Case 2012-032.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA published a proposed rule in the Federal Register at 78 FR 72620 on December 3, 2013, to revise FAR subpart 46.2, Contract Quality Requirements. The rule sought to ensure that agencies assess the risk of nonconforming items when determining whether higher-level quality standards should be used by the Government and relied on by contractors. Six respondents submitted comments on the proposed rule.

II. Discussion and Analysis

The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (the Councils) reviewed the comments in the development of the final rule. A discussion of the comments and the changes made to the rule as a result of those comments are provided as follows:

A. Summary of significant changes from the proposed rule

1. Revised FAR 46.202-4, Higher-level contract quality requirements to—

a. Clarify that higher-level quality standards include both overarching quality management system standards and product or process specific quality standards;

b. Delete reference to SAE AS6174; and

c. Add the commodity specific quality management system standard for automotive production, ISO/TS 16949.

2. Clarified that the contracting officer will list the title, number, date, and tailoring (if any) of applicable higher-level quality standard(s) in the clause prescribed at FAR 46.311.

3. Revised FAR 52.246-11, Higher-level Contract Quality Requirements, to clarify that the prime contractor is responsible for flowing down applicable requirements of the higher-level quality standard in subcontracts for critical and complex items at any tier.

B. Analysis of public comments

1. Design and Testing

Comment: One respondent recognized the need to consider "testing" and "design" as considerations for identifying higher-level contract requirements. See FAR 42.202-4(a)(1). However, the respondent seeks clarification on the inclusion of control of "design" and "testing" for complex and critical item contracts.

Response: Control of design and/or testing are complex processes that require heightened controls in many applications. While not all higher-level quality standards specify controls for design or testing some of them do, such as ISO 9001, which provides detailed requirements/guidelines concerning control of design and testing.

2. Agency Guidance

Comment: One respondent recommended that agency guidance on implementing higher-level quality requirements be completed before any new FAR policy and that it should focus on larger acquisitions to avoid the indiscriminate use of higher-level quality requirements. This respondent further recommended establishing a working group with industry to help define Governmentwide criteria for use of higher-level quality requirements so as to avoid each agency having a different policy. The same respondent recommended that contracting officer higher-level quality standards determinations be made subject to higher-level acquisition approval authority and subject matter expert concurrence and that these documents should be included in the contract file.

Response: The purpose of the rule is to ensure a considered approach to the use of higher-level quality

standards so they will not be applied indiscriminately. Agency procedures will provide guidance to the contracting officer about higher-level standards to determine when they are necessary and which standards should apply.

3. Standards List

Comment: One respondent recommended a collaborative approach between the contracting officer and the contractor when determining which higher-level quality standards apply to the prime and subcontractors. Another respondent recommended allowing contractors to have the flexibility to adopt systems and practices that reflect an appropriate standard. Another respondent recommended allowing industry to propose alternate quality standards or be given an opportunity to rebut or deviate from the standard assigned in the clause at FAR 52.246-11.

Response: This rule eliminates the ability for the offeror to indicate its selection of quality standard(s) by checking a block. This option of allowing the offeror to indicate its choice of standard was eliminated to ensure that the Government adequately assesses the necessity and appropriateness of the higher-level quality standard chosen. This rule does not change a contractor's ability to work with the Government acquisition team prior to receipt of proposals to discuss the solicitation, including

higher-level quality standards, through exchanges such as conferences, public hearings, one-on-one meetings, draft requests for proposal, etc.

Comment: One respondent recommended that FAR 46.202-4(b) state that if the FAR 52.246-11 clause is used, the cited standards will take precedence over any other higher-level quality requirements separately cited in any other contract document (e.g. Statement of Work (SOW), Contract Data Requirements).

Response: The Order of Precedence, FAR 52.212-8, clause already provides the order to follow when there is an inconsistency in the solicitation or contract and states that the contract clause takes precedence over the specifications.

4. Commercial Items

Comments: Several respondents commented that it is unclear whether higher-level quality requirements apply to commercial item/commercially available off-the-shelf item suppliers. One respondent recommended that FAR 46.202-4 and 46.311 be revised to clearly state that 52.246-11 is not to be included in contracts for commercial items.

Response: FAR 52.246-11 does not apply to commercial items or commercially available off-the-shelf items.

5. Flowdown

Comment: One respondent commented that it is unclear whether higher-level quality requirements flow down to subcontractors/suppliers, and recommended that the requirements not flow down to allow contractors to manage their own supply chain risk.

Response: Higher-level quality standards generally require contractors to apply the standards to their subcontractors. In those circumstances, the contractor is contractually obligated to comply with these standards and also ensure its subcontractors adhere. However, because the FAR clause 52.246-11 did not specifically address flowdown, the clause at 52.246-11 is being revised to clarify that the prime contractor is responsible for flowing down applicable requirements of the higher-level quality standards in subcontracts for critical and complex items, at any tier.

6. Obsolescence

Comment: One respondent recommended strengthening policy associated with obsolescence management. Another respondent recommended including new DoD policies on product obsolescence, diminishing manufacturing sources and attempts to leverage DoD expedited process for

identification and replacement of obsolete electronic parts.

Response: The FAR rule does not address obsolescence management and diminishing manufacturing sources as these areas are outside the scope of this FAR case.

7. Purchasing System Review

Comment: Respondents commented that the additional oversight of the quality management system as a part of the Contractor Purchasing System Review (CPSR) process is duplicative. One respondent indicated that industry already has strong self-governance in place to ensure compliance consisting of certification by independent bodies and Defense Contract Management Agency (DCMA), who routinely performs quality management system assessments. Also, the commenter indicated that the proposed rule does not provide guidance on how third party approvals such as AS9100 will be utilized to avoid duplication of cost and effort.

Response: Review of quality management systems as a part of the CPSR process has been a longstanding process. A third party audit establishes that the contractor has a documented process in place whereas Government Contract Quality Assurance (QA) validates that the contractor is

executing to their process. Attention to implementation of higher-level quality standards during the course of purchasing system reviews is consistent with Government Contract Quality Assurance functions and responsibilities stated in FAR part 46. It is noted that third party audits are performed by organizations that are hired by the contractor, not the Government, and who do not have formal/legal responsibilities to represent the Government's interests.

Comment: One respondent commented that higher-level quality requirements should not be part of the contractors purchasing system review because a single counterfeit incident could cause withdrawal of purchasing system approval. Another respondent recommended adding language that a deficiency solely related to the implementation of higher-level quality standards will not prevent the overall purchasing system from functioning as if approved.

Response: If the contractor is subject to a QA standard covering detection of counterfeits and a single incidence of a counterfeit part is documented as delivered during a CPSR review, the administrative contracting officer would be required to examine the circumstances to determine whether it is an isolated incident and whether the occurrence could have been prevented by the prime

contractor's proper adherence to its policies, procedures, and internal controls before withholding approval of the purchasing system (FAR 44.301 and 44.305-1).

Comment: One respondent commented that a satisfactory purchasing system should obviate the need to identify standards on individual contracts as proposed by FAR 52.246-11.

Response: There are four sections to a Quality Management System (QMS) and the purchasing system is one of six parts in one section; therefore, an acceptable purchasing system does not mean the entire QMS is acceptable.

Comment: One respondent commented that the FAR case presents unbounded content for review during a CPSR process and lacks alignment with the Defense Acquisition Regulations System (DFARS) case, which added nine elements to the CPSR process.

Response: This rule does not change the methodology for conducting a CPSR. It adds content in that, when higher-level QA is applicable to the contract, the Government will, as one part of the purchasing system review, confirm that the contractor is including appropriate quality requirements in their purchases orders. The CPSR review criteria pertaining to the implementation

of higher-level quality requirements are bounded by the applicable portions of the contractor's quality standard(s) (e.g., ISO 9001 Clause 7.4-Purchasing). This has been a long-standing process to include this review in CPSRs. The elements added to the DFARS, mentioned by the respondent, are additional elements of the CPSR for DoD coverage of a contractor's counterfeit electronic part detection and avoidance system that are not included in the FAR.

8. Risk-Based Approach

Comment: Two respondents commented that this rule takes a positive step in applying a risk-based approach to the assessment of materials entering the supply chain.

Response: Noted.

9. Scope.

Comment: One respondent recommended excluding counterfeit parts standards from higher-level quality requirements.

Response: The Councils disagree with eliminating higher-level quality standards that address counterfeit items due to the significant and growing risk, in quality, reliability, and safety that counterfeiting poses to the Government. This FAR rule case specifically removes outdated or obsolete standards and adds new examples of

higher-level quality standards, including a standard related to counterfeiting.

10. Small Business

Comment: Two respondents commented that this rule will have unintended consequences on small businesses, including small business withdrawal from the market place, which will reduce competition.

Response: This rule is not meant to limit small business participation in Government contracting; the purpose of the rule is to ensure that agencies have procedures in place to assess the risk of nonconforming items when determining whether higher-level quality standards should be used by the Government and relied on by all contractors. When contracting for complex or critical items where higher-level quality standards are necessary it would not be prudent to make exceptions based on business size.

11. Source Selection Process

Comment: One respondent recommended providing source selection policy guidance such as choice of contract type, source selection process, and evaluation of performance risk and price, when using higher-level quality requirements.

Response: The FAR subpart 15.1 outlines source selection processes and techniques that are available strategies depending on the type of acquisition. This approach allows the acquisition team to exercise discretion and use business judgment to determine the best approach for a particular acquisition.

12. Standards List

Comment: One respondent supported incorporating requirements for detection and avoidance of counterfeit electronic parts into key Quality Management Systems (QMS) standards (e.g. ISO 9000 and AS9100) and including counterfeit electronic parts avoidance and detection standards among the higher-level quality standards.

Response: Noted.

Comment: One respondent recommended that the standards listed in the proposed FAR 46.202-4(b) be more generic; also, applying examples like nuclear standards may mislead personnel into what the minimum requirements are.

Response: FAR 46.202-4(b) includes a list of examples of more specific standards to assist with selecting common standards.

Comments: One respondent recommended adding ISO/TS16949 to the list of higher-level quality standards. Another respondent supported standards that are specific to

quality management systems (e.g. AS9100, ISO9001 and AS9003) and also incorporating counterfeit parts mitigation strategies through AS5553. One respondent commented that there are a number of different standards including SAE standard AS5553, ISO 27000 series, and Open Group Trusted Technology Provider Standard that help with counterfeit avoidance and supply chain risk management.

Response: The Councils added different examples of higher-level quality standards at FAR 46.202-4(b) to allow agencies flexibility to choose the standard that best meets their quality requirements. The standards listed are examples that could be used by agencies but this list is not exhaustive. The Councils concurred with adding the commodity specific quality management system standard for automotive production, ISO/TS16949. This case further clarifies language at FAR 46.202-4(b) that higher-level quality standards include both overarching quality management system standards and product or process specific quality standards. While the rule does not add a comprehensive list of higher-level quality standards, it does not preclude the use of standards not listed in the examples at FAR 46.202-4(b).

Comments: Several respondents commented that SAE AS6174 should not be included in the list of higher-level

quality requirements since the document does not provide guidance to industry or Government in implementing meaningful counterfeit avoidance processes for material. Two respondents commented that AS6174 should not be cited as guidance as it is not mature enough to use at this stage.

Response: The Councils have accepted this comment and have deleted reference to SAE AS6174 listed in FAR 46.202-4(b).

Comments: Two respondents commented that the proposed rule extends beyond electronic parts, which is outside of section 818 requirements and recommends the Government collaborate with industry on a risk assessment of counterfeit trends to determine the extent that non-electronic parts represent a counterfeiting risk. One respondent recommended that before expanding the scope of the rule beyond electronic parts, steps should be taken to (1) collect information from Federal agencies and departments on the extent to which counterfeit material other than electronics has been identified as a cause of product or system failure; (2) call for routine assessment of trends to determine the extent to which other material commodities emerge as a significant counterfeiting risk; and (3) encourage development of standards to address other

material types. Another respondent recommended a phased-in approach to implementation to align with other section 818 regulatory cases.

Response: This rule does not directly implement any specific aspect of section 818, but recognizes the quality, reliability, and safety risk that counterfeit electronic parts represent.

This case removes outdated or obsolete standards and adds new examples of higher-level quality standards, including a standard related to counterfeiting. Contracting officers, along with technical personnel, are not restricted to the list of examples of higher-level quality standards, and may elect other standards that meet the Government's needs.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a

significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

DoD, GSA, and NASA have prepared a Final Regulatory Flexibility Analysis (FRFA) consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, et seq. The FRFA is summarized as follows:

The Government must identify items that are critical to accomplishment of the agency mission and apply higher-level quality requirements to those items. The contractor has an obligation to ensure that its deliverables meet the specified quality requirements, which also entails ensuring that its subcontractors adhere to the higher level quality standard where appropriate. This case proposes to (a) specify the higher-level quality requirement and (b) add this to the list of issues to be considered during contractor purchasing system reviews.

Two respondents expressed concern that this rule would have significant effects on small businesses, which would result in their withdrawal from participation in Government contracting. The FAR revisions made by the rule do not increase the burden on businesses, including small businesses, and the rule was not modified to allow for differing quality standards based on business size. No changes were made to the rule as a result of these comments. However, in response to another respondent, it was clarified that flowdown of the higher-level quality assurance standards will only apply to subcontracts involving critical or complex items, thus small business who do not comply with the higher level standards may still compete on other subcontracts.

Large and small businesses provide critical items directly to the Government or to Government prime contractors and these companies may be impacted by this rule. However, there is no easy way to identify the number of contracts that contain higher-level quality standards and how many of these are awarded to both large and small businesses.

Interested parties may obtain a copy of the FRFA from the Regulatory Secretariat. The Regulatory Secretariat has submitted a copy of the FRFA to the Chief Counsel for Advocacy of the Small Business Administration.

V. Paperwork Reduction Act

The final rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 44, 46, and 52

Government procurement.

Dated: November 17, 2014.

William Clark,
Acting Director,
Office of Government-wide
Acquisition Policy,
Office of Acquisition Policy,
Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR parts 44, 46, and 52 as set forth below:

1. The authority citation for 48 CFR parts 44, 46, and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

PART 44—SUBCONTRACTING POLICIES AND PROCEDURES

2. Amend section 44.303 by—

- a. Removing from the end of paragraph (i) "and";
- b. Removing from the end of paragraph (j) the period and adding "; and" in its place; and
- c. Adding paragraph (k).

The addition reads as follows:

44.303 Extent of review.

* * * * *

- (k) Implementation of higher-level quality standards.

PART 46—QUALITY ASSURANCE

3. Revise section 46.202-4 to read as follows:

46.202-4 Higher-level contract quality requirements.

(a) Agencies shall establish procedures for determining when higher-level contract quality requirements are necessary, for determining the risk (both the likelihood and the impact) of nonconformance, and for advising the contracting officer about which higher-level

standards should be applied and included in the solicitation and contract. Requiring compliance with higher-level quality standards is necessary in solicitations and contracts for complex or critical items (see 46.203) or when the technical requirements of the contract require—

(1) Control of such things as design, work operations, in-process controls, testing, and inspection; or

(2) Attention to such factors as organization, planning, work instructions, documentation control, and advanced metrology.

(b) Examples of higher-level quality standards include overarching quality management system standards such as ISO 9001, ANSI/ASQC E4, ASME NQA-1, SAE AS9100, SAE AS9003, and ISO/TS 16949, and product or process specific quality standards such as SAE AS5553.

4. Revise section 46.311 to read as follows:

46.311 Higher-level contract quality requirement.

(a) The contracting officer shall insert the clause at 52.246-11, Higher-Level Contract Quality Requirement, in solicitations and contracts when the inclusion of a higher-level contract quality requirement is necessary (see 46.202-4).

(b) For each higher-level quality standard, the contracting officer shall fill in the title, number, date, and tailoring (if any).

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

5. Revise section 52.246-11 to read as follows:

52.246-11 Higher-Level Contract Quality Requirement.

As prescribed in 46.311, insert the following clause:

HIGHER-LEVEL CONTRACT QUALITY REQUIREMENT ([INSERT ABBREVIATED MONTH AND YEAR 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER])

(a) The Contractor shall comply with the higher-level quality standard(s) listed below.

[Contracting Officer insert the title, number, date, and tailoring (if any) of the higher-level quality standards.]

(b) The Contractor shall include applicable requirements of the higher-level quality standard(s) listed in paragraph (a) of this clause and the requirement to flow down such standards, as applicable, to lower-tier subcontracts, in—

(1) Any subcontract for critical and complex items (see 46.203(b) and (c)); or

(2) When the technical requirements of a subcontract require—

(i) Control of such things as design, work operations, in-process control, testing, and inspection; or

(ii) Attention to such factors as organization, planning, work instructions, documentation control, and advanced metrology.

(End of clause)

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